Complete Summary

GUIDELINE TITLE

Continuous subcutaneous insulin infusion for the treatment of diabetes mellitus.

BIBLIOGRAPHIC SOURCE(S)

National Institute for Health and Clinical Excellence (NICE). Continuous subcutaneous insulin infusion for the treatment of diabetes mellitus. London (UK): National Institute for Health and Clinical Excellence (NICE); 2008 Jul. 30 p. (Technology appraisal guidance; no. 151).

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: National Institute for Clinical Excellence (NICE). Guidance on the use of continuous subcutaneous insulin infusion for diabetes. London (UK): National Institute for Clinical Excellence (NICE); 2003 Feb. 23 p. (Technology appraisal guidance; no. 57).

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Type 1 diabetes mellitus

GUIDELINE CATEGORY

Assessment of Therapeutic Effectiveness
Treatment

CLINICAL SPECIALTY

Endocrinology
Family Practice
Internal Medicine
Pediatrics

INTENDED USERS

Advanced Practice Nurses
Dietitians
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

To evaluate the clinical effectiveness and cost-effectiveness of continuous subcutaneous insulin infusions for the treatment of diabetes mellitus

TARGET POPULATION

Adults and children with diabetes mellitus

INTERVENTIONS AND PRACTICES CONSIDERED

Continuous subcutaneous insulin infusion (CSII) therapy for the treatment of type 1 diabetes mellitus

Note: CSII therapy is not recommended for the treatment of type 2 diabetes mellitus

MAJOR OUTCOMES CONSIDERED

- Clinical effectiveness
    - Mean glycated hemoglobin (HbA1c, %)
    - Blood glucose levels
    - Quality of life
    - Hypoglycemia
    - Insulin dose
    - Weight/body mass index (BMI)
- Cost-effectiveness

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases
Searches of Unpublished Data

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Note from the National Guideline Clearinghouse (NGC): The National Institute for Health and Clinical Excellence (NICE) commissioned an independent academic centre to perform a systematic literature review on the technology considered in this appraisal and prepare an assessment report. The assessment report for this technology appraisal was prepared by the Aberdeen Health Technology Assessment Group (see the "Availability of Companion Documents" field).

Continuous Subcutaneous Insulin Infusion (CSII) versus Best Multiple Daily Injections (MDI)

Inclusion Criteria

- Intervention: CSII
- Comparator: Best MDI – short and long-acting analogues for type 1 diabetes mellitus (T1DM), and short and long acting analogues or neutral protamine Hagedorn (NPH) for type 2 diabetes mellitus (T2DM)
- Population: T1DM and T2DM any age
- Study design: Randomised controlled trial (RCT)
- Outcomes:
    - Glycaemic control – glycated haemoglobin (HbA1c, %)
    - Blood glucose levels
    - Quality of life
    - Hypoglycaemia
    - Insulin dose
    - Weight/body mass index (BMI)

Search Strategy

Sensitive searches of electronic databases were done in order to retrieve a wide range of different types of evidence and study designs. All bibliographic records retrieved were then manually screened for studies of interest.

The following sources were used to identify both published studies and meeting abstracts:

MEDLINE, 2002-June 2007; Embase, 2002-June 2007; Science Citation Index, 2002-June 2007 (limited to meeting abstracts only); Cochrane Library 2007 Issue 1; Contact with experts Reference lists; Industry submission; Web site of ADA (American Diabetes Association) for recent meeting abstracts from the 67th Scientific Session June 22-26 2007 Chicago ILL. Searches were limited to English language only.

Ongoing and recently completed studies were searched for using National Research Register 2007 Issue 2 and Current Controlled Trials June 2007.

Details of the search strategies used and a flowchart of studies identified for clinical effectiveness are given in Appendix 3 of the Assessment Report (see the "Availability of Companion Documents" field).

Identification of Studies

Abstracts returned by the search strategy were examined independently by two researchers and screened for inclusion and exclusion. Full texts of the identified studies were obtained. Four researchers examined these independently.

NUMBER OF SOURCE DOCUMENTS

Clinical Effectiveness

A total of 74 studies were retained for data extraction and inclusion:

- 8 randomised controlled trials (RCTs) of continuous subcutaneous insulin infusion (CSII) versus best multiple drug injections (MDI) in type 1 (T1) and type 2 diabetes mellitus (T2DM)
- 8 RCTs of CSII versus neutral protamine Hagedorn (NPH) in T1DM
- 48 observational studies of CSII
- 6 studies of pumps in pregnancy
- 4 systematic reviews

Cost Effectiveness

- Eleven publications were identified -- 3 full papers and 8 abstracts
- The manufacturers provided a joint economic evaluation

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Note from the National Guideline Clearinghouse (NGC): The National Institute for Health and Clinical Excellence (NICE) commissioned an independent academic centre to perform a systematic literature review on the technology considered in this appraisal and prepare an assessment report. The assessment report for this technology appraisal was prepared by the Aberdeen Health Technology Assessment Group (see the "Availability of Companion Documents" field).

Data Extraction Strategy

Two reviewers extracted data regarding study design and characteristics, details of the intervention and patient characteristics, and outcomes into a specially designed form. Differences in data extraction were resolved by discussion, referring back to the original papers.

Quality Assessment Strategy

To assess the quality of the randomised controlled trials, the following criteria were used: (1) Method and description of randomisation; (2) Description of attrition/losses to follow up; (3) Specification of eligibility criteria; (4) Power calculation; (5) Robustness of outcome measurements; (6) Similarity of group participants at baseline; (7) Data analysis. Blinding was not used as a quality criterion in this report, as it is not possible to blind patients to the wearing of an insulin pump.

Overall study quality was rated as follows: A (all quality criteria met), B (one or more of the quality criteria only partially met), or C (one or more criteria not met).

Refer to Section 2 of the Assessment Report (see the "Availability of Companion Documents" field) for more information.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Considerations

Technology appraisal recommendations are based on a review of clinical and economic evidence.

Technology Appraisal Process

The National Institute for Health and Clinical Excellence (NICE) invites 'consultee' and 'commentator' organisations to take part in the appraisal process. Consultee organisations include national groups representing patients and carers, the bodies representing health professionals, and the manufacturers of the technology under review. Consultees are invited to submit evidence during the appraisal and to comment on the appraisal documents.

Commentator organisations include manufacturers of the products with which the technology is being compared, the National Health Service (NHS) Quality Improvement Scotland and research groups working in the area. They can comment on the evidence and other documents but are not asked to submit evidence themselves.

NICE then commissions an independent academic centre to review published evidence on the technology and prepare an 'assessment report'. Consultees and

commentators are invited to comment on the report. The assessment report and the comments on it are then drawn together in a document called the evaluation report.

An independent Appraisal Committee then considers the evaluation report. It holds a meeting where it hears direct, spoken evidence from nominated clinical experts, patients and carers. The Committee uses all the evidence to make its first recommendations, in a document called the 'appraisal consultation document' (ACD). NICE sends all the consultees and commentators a copy of this document and posts it on the NICE website. Further comments are invited from everyone taking part.

When the Committee meets again it considers any comments submitted on the ACD; then it prepares its final recommendations in a document called the 'final appraisal determination' (FAD). This is submitted to NICE for approval.

Consultees have a chance to appeal against the final recommendations in the FAD. If there are no appeals, the final recommendations become the basis of the guidance that NICE issues.

Who is on the Appraisal Committee?

NICE technology appraisal recommendations are prepared by an independent committee. This includes health professionals working in the NHS and people who are familiar with the issues affecting patients and carers. Although the Appraisal Committee seeks the views of organisations representing health professionals, patients, carers, manufacturers and government, its advice is independent of any vested interests.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A systematic review of the cost-effectiveness literature for insulin pumps conducted by the Assessment group found 11 publications. Except for one study which developed a relatively simple Markov model and another in which the model was not reported, all publications used the Centre for Outcomes Research (CORE) model. Three studies that were performed in the United Kingdom and took the health service perspective reported incremental cost-effectiveness ratios (ICERs) for continuous subcutaneous insulin infusion (CSII) therapy compared with multiple daily injections (MDI) therapy of 11,500 pounds sterling, 26,300 pounds sterling, and 32,800 pounds sterling per quality-adjusted life year (QALY) gained. In the cost-effectiveness studies, the most common assumed improvement in glycosylated haemoglobin (HbA1c) levels with CSII therapy compared with MDI therapy was 1.2%.

The base-case analysis with a reduction of HbA1c levels of 0.9% and a severe hypoglycaemic event rate of 18.7 episodes per 100 person years reduced by 50%, over a time horizon of 50 years, produced an ICER of 37,712 pounds sterling per

QALY gained for CSII compared with MDI therapy. Changing the reduction in the rate of severe hypoglycaemia events to 0% or 75% did not change the ICER significantly. With the higher baseline rate of severe hypoglycaemia assumed in the manufacturers' submission, a 50% reduction, and baseline HbA1c levels reduced to 7.9% from a baseline of 8.8%, the ICER was 36,587 pounds sterling per QALY gained. When a greater reduction in HbA1c levels of 1.4% was assumed, with no reduction in severe hypoglycaemic event rates, the ICER was 24,720 pounds sterling per QALY gained. In the cohort with good glycaemic control, when there was assumed to be no improvement in HbA1c levels but the severe hypoglycaemic event rate was 134 per 100 person years, the ICER was 273,992 pounds sterling per QALY gained for a 50% reduction and 152,058 pounds sterling per QALY gained for a 75% reduction in severe hypoglycaemia rate. Avoidance of severe hypoglycaemic events can lead to quality of life gains by avoiding the disutility of the event itself and because of the reduced fear of such events. In the scenario with a 0.9% decrease in HbA1c from a baseline of 8.8% and a 50% reduction in the rate of severe hypoglycaemia events from that in the manufacturers' submission, which was associated with an ICER of 36,587 pounds sterling, an assumed annual 0.01 quality of life increment in the CSII arm decreased the ICER to 29,300 pounds sterling per QALY gained. When the assumed quality of life increment was 0.03, the ICER decreased to 21,000 pounds sterling per QALY gained. In the cohort with good glycaemic control, when there was assumed to be no improvement in HbA1c levels, the severe hypoglycaemic event rate was 134 per 100 person years, an annual quality of life increment of 0.05 was assumed and a reduction in the rate of severe hypoglycaemia events by 50%, the ICER was 28,600 pounds sterling per QALY gained. For the same cohort but with a 75% reduction in severe hypoglycaemia events, and an annual quality of life increment of 0.04 the ICER was approximately 31,300 pounds sterling per QALY gained.

The Committee agreed that at very high baseline HbA1c levels the decrease expected with CSII could make CSII therapy cost effective because of the avoidance of long-term complications. However, at baseline levels of less than 9.0%, CSII would only be cost effective if an additional quality of life benefit was assumed. This benefit could be derived from the avoidance of the fear of hypoglycaemia as well as from other quality of life improvements associated with the use of insulin pumps themselves which were not captured in the base-case economic modelling. The Committee judged that when a plausible small quality of life benefit is assumed, CSII would be cost effective at a baseline HbA1c level of 8.5% or above, and therefore concluded that CSII therapy is recommended as a treatment option for adults with type 1 diabetes mellitus whose HbA1c levels have remained high (that is, at 8.5% or above) on MDI therapy (including, if appropriate, the use of long-acting insulin analogues) despite a high level of care.

Refer to Section 4 of the original guideline document for details of the economic analyses provided by the manufacturers, the Assessment Group, and the Appraisal Committee considerations.

METHOD OF GUIDELINE VALIDATION

External Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Consultee organizations from the following groups were invited to comment on the draft scope, Assessment Report and the Appraisal Consultation Document (ACD) and were provided with the opportunity to appeal against the Final Appraisal Determination.

- Manufacturer/sponsors
- Professional/specialist and patient/carer groups
- Commentator organisations (without the right of appeal)

In addition, individuals selected from clinical expert and patient advocate nominations from the professional/specialist and patient/carer groups were also invited to comment on the ACD.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Continuous subcutaneous insulin infusion (CSII or 'insulin pump') therapy is recommended as a treatment option for adults and children 12 years and older with type 1 diabetes mellitus provided that:

- Attempts to achieve target haemoglobin A1c (HbA1c) levels with multiple daily injections (MDIs) result in the person experiencing disabling hypoglycaemia. For the purpose of this guidance, disabling hypoglycaemia is defined as the repeated and unpredictable occurrence of hypoglycaemia that results in persistent anxiety about recurrence and is associated with a significant adverse effect on quality of life

  or

- HbA1c levels have remained high (that is, at 8.5% or above) on MDI therapy (including, if appropriate, the use of long-acting insulin analogues) despite a high level of care.

CSII therapy is recommended as a treatment option for children younger than 12 years with type 1 diabetes mellitus provided that:

- MDI therapy is considered to be impractical or inappropriate, and
- Children on insulin pumps would be expected to undergo a trial of MDI therapy between the ages of 12 and 18 years.

It is recommended that CSII therapy be initiated only by a trained specialist team, which should normally comprise a physician with a specialist interest in insulin pump therapy, a diabetes specialist nurse and a dietitian. Specialist teams should provide structured education programmes and advice on diet, lifestyle and exercise appropriate for people using CSII.

Following initiation in adults and children 12 years and older, CSII therapy should only be continued if it results in a sustained improvement in glycaemic control, evidenced by a fall in HbA1c levels, or a sustained decrease in the rate of hypoglycaemic episodes. Appropriate targets for such improvements should be set

by the responsible physician, in discussion with the person receiving the treatment or their carer.

CSII therapy is not recommended for the treatment of people with type 2 diabetes mellitus.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence supporting the recommendations is not specifically stated.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate use of continuous subcutaneous insulin infusion for the treatment of diabetes mellitus

POTENTIAL HARMS

Specific but infrequent complications of continuous subcutaneous insulin infusion (CSII) therapy include reactions and occasionally infections at the cannula site, tube blockage and pump malfunction.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- This guidance represents the view of the Institute, which was arrived at after careful consideration of the evidence available. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. The guidance does not, however, override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.
- Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to avoid unlawful discrimination and to have regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way which would be inconsistent with compliance with those duties.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

- The Healthcare Commission assesses the performance of National Health Service (NHS) organisations in meeting core and developmental standards set by the Department of Health in 'Standards for better health' issued in July 2004. The Secretary of State has directed that the NHS provides funding and resources for medicines and treatments that have been recommended by the National Institute for Health and Clinical Excellence (NICE) technology appraisals normally within 3 months from the date that NICE publishes the guidance. Core standard C5 states that healthcare organisations should ensure they conform to NICE technology appraisals.
- "Healthcare Standards for Wales" was issued by the Welsh Assembly Government in May 2005 and provides a framework both for self-assessment by healthcare organisations and for external review and investigation by Healthcare Inspectorate Wales. Standard 12a requires healthcare organisations to ensure that patients and service users are provided with effective treatment and care that conforms to NICE technology appraisal guidance. The Assembly Minister for Health and Social Services issued a Direction in October 2003 which requires local health boards and NHS trusts to make funding available to enable the implementation of NICE technology appraisal guidance, normally within 3 months.
- NICE has developed tools to help organisations implement this guidance (listed below). These are available on the NICE website (www.nice.org.uk/TA151; see also the "Availability of Companion Documents" field).
    - Slides highlighting key messages for local discussion.
    - Costing report and costing template to estimate the savings and costs associated with implementation.
    - Audit support for monitoring local practice.

IMPLEMENTATION TOOLS

Audit Criteria/Indicators
Patient Resources
Quick Reference Guides/Physician Guides
Resources
Slide Presentation

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

National Institute for Health and Clinical Excellence (NICE). Continuous subcutaneous insulin infusion for the treatment of diabetes mellitus. London (UK): National Institute for Health and Clinical Excellence (NICE); 2008 Jul. 30 p. (Technology appraisal guidance; no. 151).

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2003 Feb (revised 2008 Jul)

GUIDELINE DEVELOPER(S)

National Institute for Health and Clinical Excellence (NICE) - National Government Agency [Non-U.S.]

SOURCE(S) OF FUNDING

National Institute for Health and Clinical Excellence (NICE)

GUIDELINE COMMITTEE

Appraisal Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Committee Members: Professor David Barnett, Professor of Clinical Pharmacology, University of Leicester; Professor Mike Campbell, Professor of Medical Statistics, University of Sheffield; Dr Carol Campbell, Senior Lecturer, University of Teesside; Professor David Chadwick, Professor of Neurology, University of Liverpool; Ms Jude Cohen, Special Projects Consultant, UK Council for Psychotherapy; Dr Mike Davies, Consultant Physician, Manchester Royal Infirmary; Dr Rachel A Elliott, Lord Trent Professor of Medicines and Health, the University of Nottingham; Mrs Eleanor Grey, Lay member; Professor Peter Jones, Pro Vice Chancellor for Research & Enterprise, Keele University; Professor Jonathan Michaels, Professor of Vascular Surgery, University of Sheffield; Dr Eugene Milne, Deputy Medical Director, North East Strategic Health Authority; Dr Simon Mitchell, Consultant Neonatal Paediatrician, St Mary's Hospital, Manchester; Dr Richard Alexander, Nakielny Consultant Radiologist, Royal Hallamshire Hospital, Sheffield; Dr Katherine Payne, Health Economics Research Fellow, The University of Manchester; Dr Philip Rutledge, GP and Consultant in Medicines Management,

NHS Lothian; Professor Andrew Stevens, Chair of Appraisal Committee C and Professor of Public Health, University of Birmingham; Dr Cathryn Thomas, Senior Lecturer, Department of Primary Care & General Practice, University of Birmingham; Mr William Turner, Consultant Urologist, Addenbrooke's Hospital, Cambridge

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Committee members are asked to declare any interests in the technology to be appraised. If it is considered there is a conflict of interest, the member is excluded from participating further in that appraisal.

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: National Institute for Clinical Excellence (NICE). Guidance on the use of continuous subcutaneous insulin infusion for diabetes. London (UK): National Institute for Clinical Excellence (NICE); 2003 Feb. 23 p. (Technology appraisal guidance; no. 57).

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) format from the National Institute for Health and Clinical Excellence (NICE) Web site.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Continuous subcutaneous insulin infusion for the treatment of diabetes mellitus (review of technology appraisal guidance 57). Quick reference guide. London (UK): National Institute for Health and Clinical Excellence (NICE); 2008 Jul. 2 p. (Technology appraisal 151). Available in Portable Document Format (PDF) from the National Institute for Health and Clinical Excellence (NICE) Web site.
- Continuous subcutaneous insulin infusion for the treatment of diabetes mellitus (review of technology appraisal guidance 57). Costing template and report. London (UK): National Institute for Health and Clinical Excellence (NICE); 2008 Jul. Various p. (Technology appraisal 151). Available in Portable Document Format (PDF) from the NICE Web site.
- Continuous subcutaneous insulin infusion for the treatment of diabetes mellitus (review of technology appraisal guidance 57). Audit support. London (UK): National Institute for Health and Clinical Excellence (NICE); 2008. 8 p. (Technology appraisal 151). Available in Portable Document Format (PDF) from the NICE Web site.
- Clinical and cost-effectiveness of continuous subcutaneous infusion for diabetes: updating review. Assessment report. 2008. 258 p. Available in Portable Document Format (PDF) from the NICE Web site.

- Diabetes - insulin pump therapy: presenter slides. London (UK): National Institute for Health and Clinical Excellence (NICE); 2008 Aug. 17 p. Available from the NICE Web site.

Print copies: Available from the National Health Service (NHS) Response Line 0870 1555 455. ref: N1634. 11 Strand, London, WC2N 5HR.

PATIENT RESOURCES

The following is available:

- Insulin pump therapy for diabetes. Understanding NICE guidance - Information for people who use NHS services. London (UK): National Institute for Health and Clinical Excellence (NICE); 2008 Jul. 4 p. (Technology appraisal 151).

Electronic copies: Available in Portable Document Format (PDF) from the National Institute for Health and Clinical Excellence (NICE) Web site.

Print copies: Available from the NHS Response Line 0870 1555 455. ref: N1635. 11 Strand, London, WC2N 5HR.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

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